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510(k) Summary for the Hansson™ PinSystem Line Extension

Proprietary Name:	Hansson™ Pin System
Common Name:	Hip Fracture Fixation Device
Classification Name and Reference	Smooth or Threaded Metallic Bone Fixation Fastener 21 CFR §888.3040
Regulatory Class:	Class II
Device Product Code:	87 HTY: Pin, Fixation, Smooth
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	12/18/03

Description:
The Hansson™ Pin is a hip fracture system designed to treat various types of fractures of the proximal femur. This premarket notification is a line extension to modify the existing Hansson™ Pin System, which was cleared via K964893. The indications for use are being expanded to include additional types of proximal femoral fractures. Also, several dimension changes have been made to the predicate device's outer sleeve to improve the deployment and removal of the inner pin. In addition, the Hansson™ Pin will also be fabricated from Titanium Alloy and an end cap will be added to the product line.

Intended Use:
The Hansson™ Pin System is intended for use in the temporary stabilization of various types of fractures of the proximal femur. The subject device is indicated for fixation of proximal femoral fractures including but not limited to:

- intracapsular fractures of the femoral neck such as transcervical and subcapital neck fractures,
- basal neck fractures, and
- slipped capital femoral epiphysis (SCFE) in pediatric patients.

Substantial Equivalence:
The design and function of the Hansson™ Pin are substantially equivalent to that of the predicate devices. Both the subject and predicate Hansson™ Pin Systems offer pins in varying lengths while the ASNIS™ II & III Cannulated Bone Screws are indicated for the fixation of Slipped Capital Femoral Epiphysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Ms. Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K033968
Trade/Device Name: Hansson™ Pin System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HTY
Dated: December 18, 2003
Received: December 22, 2003

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033968

Device Name: Hansson™ Pin System

Intended Use

The Hansson™ Pin System is intended for use in the temporary stabilization of types of fractures of the proximal femur. The subject device is indicated for fixation of proximal femoral fractures including but not limited to:

- Intracapsular fractures of the femoral neck such as Transcervical and Subcapital Neck Fractures
- Basal Neck Fractures
- Slipped Capital Femoral Epiphysis (in pediatric patients)

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033968